

IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

RECEIVED

KIMBERLY PETTWAY,

Case No.

2021 DEC -3 A 9:29

Plaintiff,

DEBRA P. HACKETT, CLK
U.S. DISTRICT COURT
MIDDLE DISTRICT ALA

v.

ORIGINAL COMPLAINT

2:21-cv-802

SANOFI US SERVICES, INC. f/k/a
SANOFI-AVENTIS U.S., INC., and
SANOFI-AVENTIS U.S., LLC,

JURY TRIAL DEMANDED

Defendants.

Plaintiff Kimberly Pettway, for her Original Complaint against defendants Sanofi US Services, Inc., f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S., LLC (collectively "Sanofi"), alleges:

INTRODUCTION

1. Sanofi manufactures and sells a chemotherapy drug named Taxotere (generic name docetaxel), which is administered to many who suffer primarily from breast cancer. While it is one of many drugs effective at treating breast cancer, Sanofi has known for years that the drug carries a significant risk of causing permanent damage to the lacrimal system, including canalicular stenosis.

2. A simple preventative procedure at the onset of chemotherapy-induced tearing, involving the temporary placement of silicone stents, allows a patient to continue her Taxotere regimen while removing the likelihood of permanent damage to the lacrimal system. Although Sanofi warns that "excessive tearing which may be attributable to lacrimal duct obstruction has been reported," Sanofi failed to warn patients and oncologists of the risk that the damage can occur quickly and can be **permanent**. Further, Sanofi failed to report the severity and frequency of this risk to the Food and Drug Administration ("FDA"). Worse, Sanofi misled patients and oncologists about the severity and frequency of this devastating side effect even though this condition can be entirely preventable with early intervention and treatment during chemotherapy. As a result, Mrs. Pettway suffers from permanent injuries because she used Taxotere.

3. Plaintiff is grateful for the chemotherapy that helped to save her life; however, that gratitude is

1 diminished by the fact that she now must endure a permanent and life-altering condition that could have
2 been prevented with an adequate warning to her physicians. Plaintiff's permanent injuries to her lacrimal
3 system, specifically canalicular stenosis, have caused daily disruption to her life due to excessive tearing,
4 or epiphora. For those who have never experienced epiphora, the condition might seem like a minor
5 annoyance. However, for cancer survivors like Mrs. Pettway, the irritated, swollen, watering eyes and
6 the ongoing medical management of the condition affect their work, their self-esteem, interpersonal
7 relationships, daily activities like driving or reading a book, and their general ability to return to a normal
8 life after defeating cancer.

9 **PARTIES**

10 **A. Plaintiff**

11 4. Plaintiff Kimberly Pettway is an individual residing in Safford, Alabama who received Taxotere
12 as part of a chemotherapy regimen after being diagnosed with breast cancer. She was administered
13 Taxotere at Montgomery Cancer Center in Montgomery, Alabama. She was prescribed treatment every
14 two weeks and received a total of six infusions of Taxotere. Throughout her chemotherapy, Mrs. Pettway
15 suffered from persistent tearing which she believed was a temporary side effect of the chemotherapy.
16 Unfortunately, because no measures were taken to intervene, the tearing continued and she was ultimately
17 diagnosed with permanent canalicular stenosis.

18 **B. Sanofi Defendants**

19 5. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware corporation, with
20 a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services
21 Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A. is engaged in research and development,
22 testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of
23 prescription drugs, including Taxotere. Defendant Sanofi US Services Inc. engages in research and
24 development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or
25 distributing of prescription drugs, including Taxotere.

26 6. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with a principal
27 place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC
28 is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is Sanofi-Aventis U.S., LLC's

1 sole member. Defendant Sanofi-Aventis U.S. LLC engages in research and development, testing,
2 manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription
3 drugs, including Taxotere.

4 7. Since 2006, defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. have collectively
5 served as the U.S. operational front for Sanofi S.A. in the U.S. prescription drug market.

6 JURISDICTION AND VENUE

7 8. Federal subject matter jurisdiction is based on 28 U.S.C. §1332(a) due to the complete diversity of
8 Mrs. Pettway and Defendants and the amount in controversy exceeds \$75,000.

9 9. A substantial part of the acts and omissions giving rise to this cause of action occurred in this
10 district, in that Mrs. Pettway was administered Taxotere in the district, and therefore venue is proper here
11 pursuant to 28 U.S.C. §1391(a).

12 10. The Sanofi Defendants are subject to personal jurisdiction in this Court due to their ongoing and
13 substantial contacts in this forum.

14 FACTUAL ALLEGATIONS

15 I. Development and Approval of Taxotere (Docetaxel)

16 11. Taxotere is a drug used in the treatment of various forms of cancer, including breast cancer, and
17 is a part of a family of cytotoxic drugs referred to as taxanes. Taxanes are derived from yew trees, and
18 unlike other cytotoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the
19 structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell
20 reproduction. They are widely used as chemotherapy agents.

21 12. The FDA approved Taxotere on May 14, 1996 for limited use—namely, for the treatment of
22 patients with locally advanced or metastatic breast cancer that had either (1) progressed during
23 anthracycline-based therapy or (2) relapsed during anthracycline-based adjuvant therapy.

24 13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere “in combination
25 with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-
26 positive breast cancer.” This resulted in a greater number of patients being treated with Taxotere.

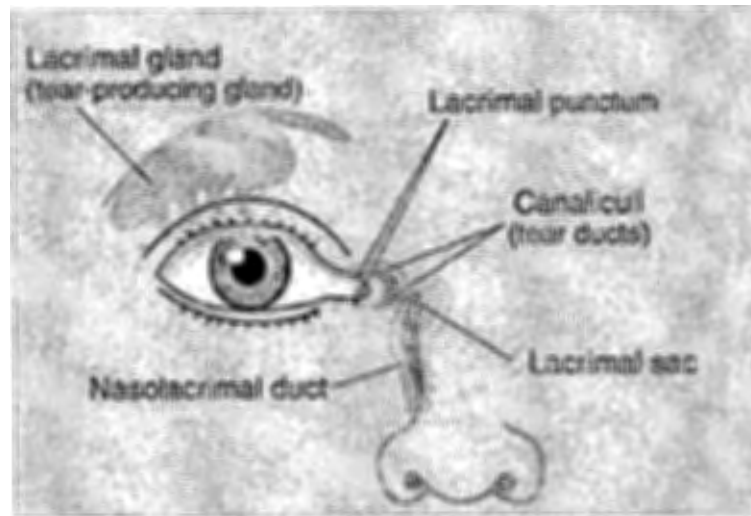
27 14. As the universe of patients taking Taxotere expanded to include patients with a higher
28 survivability rate, more cancer survivors taking Taxotere would now experience a permanent disabling

(but preventable) condition – namely, permanent damage to the lacrimal system.

15. Taxotere is not purchased by patients at a pharmacy; rather, patients' use of this drug occurs via administration through injection and/or intravenously at a physician's office or medical treatment facility.

II. Anatomy of Lacrimal System

16. The following image depicts the anatomy of the lacrimal system.



17. Taxotere is secreted in the tear film, thereby causing fibrosis in areas of the lacrimal system, including the puncta, canaliculus and/or nasolacrimal duct. This scarring can be permanent, causing an inability for tears to drain naturally through the lacrimal system. Because the eyes are constantly producing tears, this results in persistent epiphora.

III. Taxotere's Labeling

18. At the time Mrs. Pettway was administered Taxotere, its labeling information stated in relevant part under **Post-Marketing Experiences**:

Ophthalmologic: conjunctivitis, lacrimation or lacrimation with or without conjunctivitis. Excessive tearing which may be attributable to lacrimal duct obstruction has been reported. Rare cases of transient visual disturbances (flashes, flashing lights, scotomata) typically occurring during drug infusion and in association with hypersensitivity reactions have been reported. These were reversible upon discontinuation of the infusion.

and under **Patient Counseling Information**:¹

- Explain to patients that side effects such as nausea, vomiting, diarrhea, constipation, fatigue, excessive tearing, infusion site reactions, and hair loss are associated with docetaxel administration.

¹ https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020449s0631bl.pdf

1
2 19. Additionally, in the *Patient Information* section of the label, Sanofi includes “redness of the eye,
3 excess tearing” among “the most common side effects of Taxotere.” *Id.* Sanofi’s inclusion of this
4 potentially permanent side effect in a laundry list of common but notably transitory side effects
5 effectively misrepresents the risk of harm associated with tearing. By failing to fully inform patients and
6 physicians of the potential for serious permanent damage to the lacrimal system, Sanofi downplays the
7 significance of the underlying injury causing the patient to tear.

8 20. Sanofi’s labeling information at all times relevant to this lawsuit, and even to date, does not
9 identify the risk of stenosis as a cause of excessive tearing, the rapid onset at which stenosis can occur,
10 the potentially permanent nature of the injury, the need to refer patients to a lacrimal specialist, nor does
11 it identify the condition as preventable with timely intervention during chemotherapy.

12 21. Sanofi did not provide such adequate notice to oncologists. To the contrary, the labeling leads
13 oncologists, like Mrs. Pettway’s, to believe that excessive tearing is merely a transitory side effect and
14 will end after the cessation of chemotherapy. This failure to provide notice resulted in thousands of
15 women, like Mrs. Pettway, suffering daily from a permanent condition that could have easily been
16 prevented with adequate warning.

17 **IV. Sanofi’s Duty to Monitor and Update Labeling**

18 22. The primary responsibility for timely communicating complete, accurate, and current safety and
19 efficacy information related to Taxotere rests with Sanofi because it has superior, and in many cases
20 exclusive, access to the relevant safety and efficacy information, including post-market complaints and
21 data.

22 23. To fulfill its essential responsibilities, Sanofi must vigilantly monitor all reasonably available
23 information. It must closely evaluate the post-market clinical experience of its drugs and timely provide
24 updated safety and efficacy information to the healthcare community and to consumers.

25 24. When monitoring and reporting adverse events, as required by both federal regulations and state
26 law, time is of the essence. The purpose of monitoring a product’s post-market experience is to detect
27 potential safety signals that could indicate to drug sponsors and the medical community that a public
28 safety problem exists.

1 25. If, for example, a manufacturer was to delay reporting post-market information, that delay could
2 mean that researchers, FDA, and the medical community are years behind in identifying a public safety
3 issue associated with the drug.

4 26. In the meantime, more patients are harmed by using the product without knowing, understanding,
5 and accepting its true risks, which is why drug sponsors must not only completely and accurately monitor,
6 investigate and report post-market experiences, but must also report the data in a timely fashion.

7 27. A drug is “misbranded” in violation of the FDCA when its labeling is false and misleading or
8 does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a),
9 (b), (k); 352(a), (f). A drug’s labeling satisfies federal requirements if it gives physicians and pharmacists
10 sufficient information—including indications for use and “any relevant hazards, contraindications, side
11 effects, and precautions”—to allow those professionals “to use the drug safely and for the purposes for
12 which it is intended.” 21 C.F.R. § 201.100(c)(1).

13 28. As part of their responsibility to monitor post-market clinical experiences with the drug and
14 provide updated safety and efficacy information to the healthcare community and to consumers, each
15 approved NDA applicant “must promptly review all adverse drug experience information obtained or
16 otherwise received by the applicant from any source, foreign or domestic, including information derived
17 from commercial marketing experience, post marketing clinical investigations, post marketing
18 epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific
19 papers.” 21 C.F.R. § 314.80(b).

20 29. Any report of a “serious and unexpected” drug experience, whether foreign or domestic, must be
21 reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. §
22 314.80(c)(1)(i-ii).

23 30. Most other adverse event reports must be submitted quarterly for three years after the application
24 is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a
25 “history of actions taken since the last report because of adverse drug experiences (for example, labeling
26 changes or studies initiated).” 21 C.F.R. § 314.80(c)(2)(ii).

27 31. Federal law requires labeling to be updated as information accumulates: “labeling must be revised
28 to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a

1 causal association with a drug; a causal relationship need not have been definitely established.” 21 C.F.R.
2 § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is
3 “some basis to believe there is a causal relationship between the drug and the occurrence of the adverse
4 event.” 21 C.F.R. § 201.57(c)(7).

5 32. All changes to drug labels require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug
6 sponsors may seek to change their approved labels by filing a supplemental application. 21 C.F.R. §
7 314.70.

8 33. One regulation, the “Changes Being Effected” (CBE) regulation, permits a manufacturer to
9 unilaterally change a drug label to reflect “newly acquired information,” subject to later FDA review and
10 approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes “new analyses of previously
11 submitted data.” 21 C.F.R. § 314.3(b).

12 34. Thus, for instance, if a drug sponsor determined that a warning was insufficient based on a new
13 analysis of previously existing data, it could submit a CBE and change its labeling.

14 35. The longer a drug sponsor delays updating its labeling to reflect current safety information, the
15 more likely it is that medical professionals will prescribe the drug without advising patients of harmful
16 adverse reactions, and the more likely it is that patients will suffer harmful side effects without the
17 opportunity to evaluate risks for themselves.

18 **V. Sanofi Knew That Taxotere Can Cause Permanent Canalicular Stenosis.**

19 36. Since 2002, Sanofi’s Taxotere label has advised that “excessive tearing which may be
20 attributable due to lacrimal obstruction has been reported.”² Despite this language, medical literature
21 has continued to accumulate and raise concerns that oncologists are not being properly warned of the
22 severity of this permanent side effect – and in response, Sanofi has done nothing to notify oncologists
23 or patients.

24 37. The following studies, published after 2002, highlight concerns of the increased frequency and
25 severity of permanent stenosis in cancer patients taking Taxotere, the increased need for monitoring,
26 and the lack of awareness among oncologists and their patients regarding the true nature of the damage
27 caused:

28 _____
² https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020449s0631bl.pdf

1 a) From *American Society of Ophthalmic Plastic and Reconstructive Surgery*:

2 Better education of oncologists who prescribe docetaxel is
3 needed as we continue to encounter new cases of advanced
4 canalicular blockage.³

5 b) From *American Cancer Society*:

6 Despite the previous publication of several articles by our
7 group regarding canalicular stenosis and lacrimal
8 obstruction resulting from docetaxel therapy, we still
9 frequently encounter advanced cases of this condition
because of delayed diagnosis. Thus it appears that
oncologists need to become better educated regarding this
side effect.

10 All patients receiving weekly docetaxel should be monitored
11 closely by an ophthalmologist so that the timely
12 management of canalicular stenosis can be offered.

13 We recommend silicone intubation [stents] in all
14 symptomatic patients who are receiving weekly docetaxel if
they are to continue receiving the drug.⁴

15 c) From *Pharmacotherapy*:

16 Moreover, epiphora may be an underrecognized adverse
17 effect of docetaxel because excess tearing after
18 chemotherapy administration is not as stringently monitored
19 as life-threatening toxicities . . . This adverse effect warrants
20 evaluation because weekly administration is being used
more commonly for the treatment of advanced solid tumors,
and epiphora can interfere with the activities and quality of
daily life.⁵

21 d) From the *Journal of Clinical Oncology*:

22 Despite substantial literature documenting canalicular
23 stenosis as an adverse effect of docetaxel, the exact
24 incidence of this important adverse effect is unknown. All

25 ³ Bitá Esmaeli, et al., *Docetaxel-Induced Histologic Changes in the Lacrimal Sac and Nasal Mucosa*,
19 OPTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY 4, pp. 305-308 (2003)

26 ⁴ Bitá Esmaeli, et al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
27 *Therapy*, 98 CANCER 504-7 (2003)

28 ⁵ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

previous publications were based on retrospective studies at tertiary ophthalmology practices, and only patients whose symptoms of epiphora were evaluated. We report the finding of prospective, single-center study designed to determine the incidence and severity of epiphora and its anatomic correlate, canalicular stenosis, in patients receiving docetaxel weekly or every 3 weeks.

Previous retrospective studies and our clinical experience suggested that the incidence of epiphora might be as high as 50% in patients treated with weekly docetaxel and less than 10% in patients who receive docetaxel every 3 weeks.

In this prospective, observational study, epiphora was seen in 64% of patients in the weekly docetaxel group and in 39% of the docetaxel every 3 weeks group.

Patients who experience epiphora associated with docetaxel should be promptly referred to an ophthalmologist familiar with this adverse effect. Frequent [approximately every 4-6 weeks] probing and irrigation in the office and judicious use of topical steroids on a tapering dose can eliminate the need for silicone intubation or other lacrimal procedures in approximately 80% of patients taking docetaxel every 3 weeks and in approximately 50% of patients taking docetaxel weekly.⁶

38. Prominent medical researchers have described this side effect as follows: “canalicular stenosis may be the most important side effect of weekly docetaxel;”⁷ “cancer patients . . . view epiphora as one of the worst side effects because of their inability to read, drive, or wear make-up;”⁸ “visually disabling;”⁹ “misleading appearance of emotional tears;”¹⁰ “canalicular stenosis can negatively impact

⁶ Bitá Esmaeli, et al., *Prospective Study of Incidence and Severity of Epiphora and Canalicular Stenosis in Patients With Metastatic Breast Cancer Receiving Docetaxel*, 24 JOURNAL OF CLINICAL ONCOLOGY 22 (2006).

⁷ Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

⁸ *Id.*

⁹ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly versus Every-3-Weeks Docetaxel in Patients with Metastatic Breast Cancer*, 109 AM ACAD. OF OPHTHALMOLOGY, 1188 (2002).

¹⁰ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable Side Effect*, 13 EUROPEAN SOC'Y. FOR MED. ONCOLOGY, 218 (2001).

the quality of life . . . and should be considered when choosing the chemotherapy regimen;”¹¹ “epiphora may be a major disability. It interferes with daily activities and causes emotional disturbances;”¹² “the potential risk of this complication should be carefully weighed;”¹³ “epiphora may be an underrecognized adverse effect;”¹⁴ and “the high incidence of this adverse effect has an impact on several aspects of daily living.”¹⁵

39. Medical literature is clear that: (1) the onset of damage to the lacrimal system can be rapid upon initiation of Taxotere administration, (2) immediate referral to a lacrimal specialist for monitoring is essential, (3) damage to the lacrimal system can be permanent, (4) this side effect is preventable, and (5) oncologists are not aware of the severity of this side effect. Unfortunately, this lack of awareness often results in oncologists counseling their patients that their tearing is a temporary side effect and will eventually subside.

VI. Taxotere Caused Mrs. Pettway’s Permanent Canalicular Stenosis

40. Mrs. Pettway was diagnosed with breast cancer and given chemotherapy with Taxotere, receiving a total of six infusions over the course of three months.

41. During the course of her chemotherapy treatment, Mrs. Pettway suffered from a number of side effects to her chemotherapy. Among these, she experienced significant tearing.

42. Mrs. Pettway completed chemotherapy and was excited to be cancer free and rid of all the side effects she suffered as a result of the cancer treatment. Among these, Mrs. Pettway looked forward to no longer suffering from constantly irritated, watering eyes. But as the effects of chemotherapy wore off, her watery eyes remained.

43. Mrs. Pettway continued to experience persistent tearing and a disruption of her life. As a direct

¹¹ Bitá Esmali, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 AM. CANCER SOC’Y., 504 (2003).

¹² Medy Tsalic, et al., *Epiphora (Excessive Tearing) and Other Ocular Manifestations Related to Weekly Docetaxel*, 23 MEDICAL ONCOLOGY (2005).

¹³ *Id.*

¹⁴ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

¹⁵ Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving Adjuvant Docetaxel-based Chemotherapy*, 31 JOURNAL OF CLINICAL ONCOLOGY, 17 (2013)

1 and proximate result of Sanofi's conduct in connection with the design, development, manufacture,
2 testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of
3 Taxotere, Mrs. Pettway suffered from epiphora due to permanent canalicular stenosis. This condition is
4 known by Sanofi to be a permanent side effect of taking Taxotere.

5 44. Mrs. Pettway sought treatment from an optometrist, who advised her that her watery eyes were
6 caused by allergies and irritation, and was given drops to relieve the tearing.

7 45. As a result of this permanent side effect, Mrs. Pettway struggled to return to normalcy, because
8 even after surviving cancer her epiphora interfered with her ability to perform basic activities and enjoy
9 life. This permanent change altered Mrs. Pettway's self-image, negatively impacted her relationships,
10 and others' perceptions of her, leading to social isolation even long after fighting cancer.

11 46. Mrs. Pettway's tearing has impacted all aspects of her daily life. Prior to developing permanent
12 canalicular stenosis, Mrs. Pettway was self-confident and enjoyed social and professional interactions
13 with other people. Epiphora caused her to feel ashamed and lack the confidence she previously enjoyed.

14 47. Mrs. Pettway's tears caused her vision to be blurry to such an extent that she could barely see
15 especially when driving or doing everyday household duties. In addition, the epiphora caused itching and
16 discomfort due to the need to wipe and rub her eyes.

17 48. Mrs. Pettway's injuries could have been prevented had Sanofi simply warned that permanent
18 canalicular stenosis is a common but preventable side effect of Taxotere. Specifically, had Sanofi
19 properly warned Mrs. Pettway's oncologist of the rapid onset of permanent damage, her oncologist would
20 stressed the seriousness of this side effect and referred her immediately to a qualified lacrimal specialist.
21 Mrs. Pettway thus seeks recovery for her mental and physical suffering stemming from permanent, but
22 easily preventable, canalicular stenosis.

23 49. Mrs. Pettway files this lawsuit within the applicable statute of limitations.

24 **VII. Tolling of the Statute of Limitations.**

25 50. Alternatively, Mrs. Pettway files this lawsuit within the applicable statute of limitations period of
26 first suspecting that Sanofi's wrongful conduct caused the appreciable harm she sustained. Due to
27 Sanofi's fraudulent concealment of the true nature of "excessive tearing which may be attributable to
28 lacrimal duct obstruction," Mrs. Pettway could not, by the exercise of reasonable diligence, have

1 discovered that Sanofi wrongfully caused her injuries since she was unaware of the severity and
2 permanency of her injury. Specifically in its warning label, which Sanofi intended for oncologists to read
3 and rely on, Sanofi fraudulently concealed (1) the rapid onset at which stenosis can occur, (2) the
4 potentially permanent nature of the injury, (3) the need to immediately refer patients to a lacrimal
5 specialist and (4) that the condition is highly preventable with timely intervention during chemotherapy.
6 As a result, Mrs. Pettway was unaware that Sanofi knew of the devastating and permanent consequences
7 of stenosis, or that Sanofi concealed this information from her oncologist. Because Mrs. Pettway's
8 oncologist was unaware of the permanent nature of this side effect, Mrs. Pettway was also unaware that
9 her condition was permanent.

10 51. Sanofi to this day does not warn that Taxotere can cause **permanent** obstruction of the lacrimal
11 system. Therefore Mrs. Pettway did not suspect, nor did she have reason to suspect, that she had been
12 permanently injured. Because Sanofi failed to warn Mrs. Pettway's oncologist, Mrs. Pettway's oncologist
13 was unable to advise her of the true nature of her condition. Thereafter, in seeking treatment for her
14 epiphora, Mrs. Pettway was advised by an optometrist that her epiphora was caused by allergies and
15 irritation. As such, Mrs. Pettway did not and could not suspect the tortious nature of the conduct causing
16 her injuries until a date before filing this action that is less than the applicable limitations period for filing
17 suit.

18 52. In 2019, Mrs. Pettway contacted Hotze Runkle law firm after seeing a Facebook post regarding
19 the connection between Taxotere and epiphora. Mrs. Pettway read that the manufacturers of Taxotere
20 were aware of permanent damage to the lacrimal system, but they intentionally withheld this information
21 from healthcare practitioners and consumers. Mrs. Pettway sought treatment from an oculoplastic
22 surgeon, who diagnosed her with canalicular stenosis in December 2019. Only then did Mrs. Pettway
23 know that her epiphora was not a result of allergies, but was instead due to permanent damage to her
24 lacrimal system caused by Taxotere. On December 18th, Mrs. Pettway underwent an invasive
25 canaliculoplasty surgery in an attempt to alleviate her epiphora.

26 53. Additionally, Mrs. Pettway was prevented from discovering this information at an earlier date
27 because Sanofi: (1) misrepresented to the public, the FDA, and the medical profession the permanent
28 nature of "lacrimal duct obstruction;" (2) failed to disclose to the public, the FDA, and the medical

1 profession its knowledge of the risk of permanent but reversible side effects; (3) failed to disclose to the
2 public, the FDA, and the medical profession its knowledge that these side effects were preventable with
3 early intervention during chemotherapy; (4) fraudulently concealed facts and information that could have
4 led Mrs. Pettway to discover Sanofi's liability; and (5) still has not disclosed to the public, the FDA, and
5 the medical profession that Taxotere can cause permanent punctal, canalicular and nasolacrimal duct
6 stenosis which can be prevented with early intervention during chemotherapy.

7 **COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)**

8 54. Mrs. Pettway incorporates by reference the above paragraphs as if set forth herein.

9 55. At all relevant times, Sanofi was in the business of designing, researching, manufacturing, testing,
10 promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere used
11 by Mrs. Pettway.

12 56. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed,
13 supplied and/or placed into the stream of commerce by Sanofi failed to provide adequate warnings to
14 users and their healthcare providers, including Mrs. Pettway and her healthcare providers, of the risk of
15 side effects associated with the use of Taxotere, particularly the risk of developing disfiguring, permanent
16 canalicular stenosis, or the measures that could have been taken to prevent it. The Taxotere designed,
17 formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream
18 of commerce by Sanofi and ultimately administered to Mrs. Pettway lacked such warnings when it left
19 Sanofi's control.

20 57. The risks of developing disfiguring, permanent canalicular stenosis were known to or reasonably
21 knowable by Sanofi at the time the Taxotere left Sanofi's control, because of "newly acquired
22 information" available to Sanofi after the 2002 label change.

23 58. A reasonably prudent company in the same or similar circumstances would have provided a
24 warning that communicated the dangers and safe use of Taxotere.

25 59. Any warnings actually provided by Sanofi did not sufficiently and/or accurately reflect the
26 symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing
27 disfiguring, permanent canalicular stenosis or how it could have been prevented during administration of
28 the chemotherapy.

1 60. Without adequate warning of these side effects, Taxotere is not reasonably fit, suitable, or safe
2 for its reasonably anticipated or intended purposes.

3 61. Mrs. Pettway was a reasonably foreseeable user of Taxotere who used the drug in a reasonably
4 anticipated manner.

5 62. Mrs. Pettway would have taken preventative measures during her chemotherapy to prevent
6 canalicular stenosis had Sanofi provided an adequate warning of the risk of these side effects.

7 63. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse
8 effects of Taxotere, Mrs. Pettway suffered and continues to suffer serious and dangerous side effects,
9 severe and personal injuries that are permanent and lasting in nature, and economic and non-economic
10 damages, harms, and losses, including, but not limited to: past and future medical expenses; past and
11 future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement,
12 including canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk
13 of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past,
14 present, and future loss and impairment of the quality and enjoyment of life.

15 WHEREFORE, Plaintiff Kimberly Pettway respectfully requests judgment in her favor and against
16 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
17 this Court deems just and proper.

18 **COUNT II – STRICT PRODUCTS LIABILITY (MISREPRESENTATION)**

19 64. Mrs. Pettway incorporates by reference the above paragraphs as if set forth herein.

20 65. Sanofi sold the Taxotere that Mrs. Pettway's healthcare providers prescribed for Mrs. Pettway
21 and that Mrs. Pettway used.

22 66. Sanofi was engaged in the business of selling the Taxotere for resale, use, or consumption.

23 67. Sanofi misrepresented facts as set forth herein concerning the character or quality of the Taxotere
24 that would be material to potential prescribers and purchasers or users of the product.

25 68. Sanofi's misrepresentations were made to potential prescribers and/or purchasers or users as
26 members of the public at large.

27 69. As purchasers or users, Mrs. Pettway and her healthcare providers reasonably relied on the
28 misrepresentations.

1 70. Mrs. Pettway was a person who would reasonably be expected to use, consume, or be affected by
2 the Taxotere.

3 71. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Pettway
4 to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting
5 in nature, and economic and non-economic damages, harms, and losses, including, but not limited to:
6 past and future medical expenses; past and future loss of earnings; past and future loss and impairment
7 of earning capacity; permanent disfigurement, including permanent punctal stenosis; mental anguish;
8 severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical
9 and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the
10 quality and enjoyment of life.

11 WHEREFORE, Kimberly Pettway respectfully requests judgment in her favor and against
12 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
13 this Court deems just and proper.

14 **COUNT III – NEGLIGENCE**

15 72. Mrs. Pettway incorporates by reference the above paragraphs as if set forth herein

16 73. Sanofi had a duty to exercise reasonable care in the design, research, formulation, manufacture,
17 production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Taxotere,
18 including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and
19 dangerous side effects.

20 74. Sanofi breached these duties when it put Taxotere into interstate commerce, unreasonably and
21 without adequate and/or proper warning to Mrs. Pettway and her healthcare providers, a product that
22 Sanofi knew or should have known created a high risk of unreasonable, disfiguring, and dangerous side
23 effects.

24 75. The negligence of Sanofi, its agents, servants, and/or employees, included but was not limited to,
25 the following acts and/or omissions:

- 26 (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Taxotere
27 without thoroughly, adequately, and/or sufficiently testing it — including pre-clinical and
28 clinical testing and post-marketing surveillance — for safety and fitness for use and/or its
dangers and risks;

- (b) Marketing Taxotere to Mrs. Pettway, her healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects, including permanent canalicular stenosis;
- (c) Marketing Taxotere to the public, and the medical and healthcare professions without providing adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Taxotere;
- (d) Advertising and recommending the use of Taxotere without sufficient knowledge of its safety profile;
- (e) Designing, manufacturing, producing, and/or assembling Taxotere in a manner that was dangerous to its users;
- (f) Concealing information from Mrs. Pettway, her healthcare providers, the public, other medical and healthcare professionals, and the FDA that Taxotere was unsafe, dangerous, and/or non-conforming with FDA regulations;
- (g) Concealing from and/or misrepresenting information to Mrs. Pettway, her healthcare providers, other medical and healthcare professionals, and/or the FDA concerning the existence and severity of risks and dangers of Taxotere; and
- (h) Encouraging the sale of Taxotere, either directly or indirectly, orally or in writing, to Mrs. Pettway and her healthcare providers without warning about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects such as punctal, canalicular and nasolacrimal duct stenosis.

76. Despite the fact that Sanofi knew or should have known that Taxotere caused unreasonably dangerous side effects, Sanofi continues to market, manufacture, distribute, and/or sell Taxotere to consumers.

77. Mrs. Pettway and her healthcare providers were therefore forced to rely on safety information that did not accurately represent the risks and benefits associated with the use of Taxotere and measures that could have been taken to prevent severe and permanent disfigurement from the use of Taxotere.

78. Sanofi knew or should have known that consumers such as Mrs. Pettway would use its product and would foreseeably suffer injury as a result of Sanofi's failure to exercise reasonable care.

79. Sanofi's negligence was a proximate cause of Mrs. Pettway's injuries, harms, damages, and losses, in connection with the use of Taxotere, including but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent canalicular stenosis; mental anguish; severe and

1 debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental
2 pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and
3 enjoyment of life.

4 WHEREFORE, Kimber Pettway respectfully requests judgment in her favor and against Defendants
5 in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
6 deems just and proper.

7 **COUNT IV – NEGLIGENT MISREPRESENTATION**

8 80. Mrs. Pettway incorporates by reference the above paragraphs as if set forth herein.

9 81. Sanofi had a duty to represent to Mrs. Pettway, her healthcare providers, the healthcare
10 community, and the public in general that Taxotere had been tested and found to be safe and effective for
11 the treatment of various forms of cancer.

12 82. When warning of safety and risks of Taxotere, Sanofi negligently represented to Mrs. Pettway,
13 her healthcare providers, the healthcare community, and the public in general that Taxotere had been
14 tested and was found to be safe and/or effective for its indicated use.

15 83. Sanofi concealed its knowledge of Taxotere defects from Mrs. Pettway, her healthcare providers,
16 and the public in general and/or the healthcare community specifically.

17 84. Sanofi concealed this information with the intent of defrauding and deceiving Mrs. Pettway, her
18 healthcare providers, the public in general, and the healthcare community in particular, and were made
19 with the intent of inducing Mrs. Pettway, her healthcare providers, the public in general, and the
20 healthcare community in particular, to recommend, dispense, and/or purchase Taxotere.

21 85. Sanofi failed to exercise ordinary and reasonable care in its representations of Taxotere in its sale,
22 testing, quality assurance, quality control, and/or distribution into interstate commerce, and Sanofi
23 negligently misrepresented Taxotere's high risks of unreasonable, dangerous side effects. These side
24 effects were unreasonable because they could have been entirely prevented with adequate warning.

25 86. Sanofi breached its duty in misrepresenting Taxotere's serious side effects to Mrs. Pettway, her
26 healthcare providers, the healthcare community, the FDA, and the public in general.

27 87. Mrs. Pettway and her healthcare providers reasonably relied on Sanofi to fulfill its obligations to
28 disclose all facts within its knowledge regarding the serious side effects of Taxotere and the ability to

1 prevent those side effects with appropriate precautionary measures.

2 88. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Pettway
3 to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting
4 in nature, and economic and non-economic damages, harms, and losses, including, but not limited to:
5 past and future medical expenses; past and future loss of earnings; past and future loss and impairment
6 of earning capacity; permanent disfigurement, including permanent canalicular stenosis; mental anguish;
7 severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical
8 and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the
9 quality and enjoyment of life.

10 WHEREFORE, Kimberly Pettway respectfully requests that judgment in her favor and against
11 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
12 this Court deems just and proper.

13 COUNT V – FRAUDULENT MISREPRESENTATION

14 89. Mrs. Pettway incorporates by reference the above paragraphs as if set forth herein.

15 90. In its labeling information, Sanofi communicated to Mrs. Pettway, her healthcare providers, the
16 healthcare community, and the public in general that “excessive tearing which may be attributable to
17 lacrimal duct obstruction has been reported” and that excessive tearing is a common side effect. These
18 statements misrepresented the true risk of harm to patients, in that they failed to fully inform oncologists
19 and patients of (1) the rapid onset at which stenosis can occur, (2) the potentially **permanent** nature of
20 the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition is
21 highly preventable with timely intervention during chemotherapy.

22 91. Despite having knowledge of this side effect, Sanofi fraudulently omitted from this vague
23 warning of “lacrimal duct obstruction” and/or “excessive tearing” that Taxotere could and did cause
24 **permanent** damage to the lacrimal system, including canalicular stenosis.

25 92. These representations were material and false.

26 93. Sanofi made these representations and omissions:

- 27 (a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or
28 belief of falsity of the resulting statements;

1 (b) positively and recklessly without knowledge of their truth or falsity;

2 (c) with knowledge that they were made without any basis; and/or

3 (d) without confidence in the accuracy of the representations or statements resulting from the
4 omissions.

5 94. Sanofi made these false representations with the intention or expectation that Mrs. Pettway, her
6 healthcare providers, the public in general, and the healthcare community in particular, would
7 recommend, dispense, and/or purchase Taxotere, all of which evidenced a callous, reckless, willful,
8 wanton, and depraved indifference to the health, safety, and welfare of Mrs. Pettway.

9 95. At the time Sanofi made the aforesaid representations, and, at the time Mrs. Pettway used
10 Taxotere, Mrs. Pettway and her healthcare providers were unaware of the falsity of Sanofi's
11 representations, statements and/or implications and justifiably and reasonably relied on Sanofi's
12 representations, statements, and implications, believing them to be true.

13 96. In reliance on Sanofi's representations, Mrs. Pettway and her healthcare providers were induced
14 to and did use and prescribe Taxotere, which caused Mrs. Pettway to suffer serious and dangerous side
15 effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-
16 economic damages, harms, and losses, including, but not limited to: past and future medical expenses;
17 past and future loss of earnings; past and future loss and impairment of earning capacity; permanent
18 disfigurement, including permanent canalicular stenosis; mental anguish; severe and debilitating
19 emotional distress; increased risk of future harm; past, present, and future physical and mental pain,
20 suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment
21 of life.

22 WHEREFORE, Kimberly Pettway respectfully requests judgment in her favor and against
23 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
24 this Court deems just and proper.

25 **COUNT VI – FRAUDULENT CONCEALMENT**

26 97. Mrs. Pettway incorporates by reference the above paragraphs as if set forth herein.

27 98. At all times during the course of dealing between Sanofi and Mrs. Pettway and her healthcare
28 providers, Sanofi misrepresented the design characteristic and safety of Taxotere for their intended use.

1 99. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi's
2 access to ongoing studies and reports that disclosed serious, but preventable damage to the lacrimal
3 system caused by Taxotere. In representations made to Mrs. Pettway and her healthcare providers, Sanofi
4 fraudulently concealed and intentionally omitted the following material information: (1) the rapid onset
5 at which stenosis can occur, (2) the potentially permanent nature of the injury, (3) the need to immediately
6 refer patients to a lacrimal specialist and (4) that the condition is highly preventable with timely
7 intervention during chemotherapy.

8 100. Sanofi had a duty to disclose to Mrs. Pettway and her healthcare providers the defective nature
9 of Taxotere, including, but not limited to, the heightened risks of disfiguring, permanent canalicular
10 stenosis.

11 101. Sanofi had a duty to disclose to Mrs. Pettway and her healthcare providers that the disfiguring,
12 permanent canalicular stenosis caused by the use of Taxotere could have been prevented by early
13 identification and treatment of epiphora during chemotherapy.

14 102. Sanofi had sole access to material facts concerning the defective nature of Taxotere and its
15 propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used
16 the drugs at issue, including Mrs. Pettway.

17 103. Sanofi's concealment and omissions of material fact concerning the safety of Taxotere were
18 made purposefully, willfully, wantonly, and/or recklessly to mislead Mrs. Pettway and her healthcare
19 providers into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or
20 dispense Taxotere and/or use it.

21 104. Sanofi knew that Mrs. Pettway and her healthcare providers had no way to determine the truth
22 behind its concealment and omissions, including the material omissions of fact surrounding Taxotere set
23 forth herein.

24 105. Mrs. Pettway and her healthcare providers reasonably relied on information disclosed by Sanofi
25 that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or
26 omitted by Sanofi.

27 106. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Pettway to suffer serious
28 and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and

1 economic and non-economic damages, harms, and losses, including, but not limited to: past and future
2 medical expenses; past and future loss of earnings; past and future loss and impairment of earning
3 capacity; permanent disfigurement, including permanent canalicular stenosis; mental anguish; severe and
4 debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental
5 pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and
6 enjoyment of life.

7 WHEREFORE, Kimberly Pettway respectfully requests judgment in her favor and against
8 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
9 this Court deems just and proper.

10 **VIII. JURY DEMAND**

11 Plaintiff has requested a trial by jury pursuant to rule 38 of the Federal Rules of Civil Procedure.
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13
14

15 Dated: December 2, 2021

HENINGER GARRISON DAVIS, LLC

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